

page 8, lines 3 and 4. Support for the new claim 25 may be found *inter alia* in the subject application, as originally-filed, at page 8, lines 16 and 17. Applicants respectfully request that this Amendment be entered.

35 U.S.C. §102(b) Rejection

On page 3 of the September 24, 2002 Office Action, the Examiner rejected claims 10 to 13 under 35 U.S.C. 102(b) as anticipated by Nakoneczny et. al. (U.S. Patent 5,242,111), hereinafter "Nakoneczny". Applicants respectfully submit that the present invention is not anticipated by Nakoneczny and request reconsideration.

The Examiner alleged that Nakoneczny teaches an apparatus comprising a storage compartment that is compressible by mechanical pressure and containing fluid therein, a dermal patch in fluid communication with said storage compartment, having a plurality of hollow capillaries for flow of said fluid and attached to a portion of skin of a patient and a regulating valve for flow control of fluid from said storage compartment.

Independent claim 10 recites:

Apparatus for transdermal delivery of a substance for treatment of Parkinson's disease, said apparatus comprising:

a storage compartment containing therein a fluid for transdermal treatment of Parkinson's disease; and

a dermal patch in fluid communication with said storage compartment, said dermal patch being attached to a portion of skin of a patient, wherein said fluid flows from said storage compartment to said dermal patch and is thence transdermally delivered to said patient.

New Independent claim 22 recites:

Apparatus for transdermal delivery of a substance, said apparatus comprising:

a storage compartment containing therein a fluid; and

a dermal patch in fluid communication with said storage compartment, said dermal patch being attached to a portion of skin

of a patient, wherein said fluid flows from said storage compartment to said dermal patch and is thence transdermally delivered to said patient.

Under 35 U.S.C. § 102, an invention can only be anticipated by a reference that identically discloses every feature of the claimed invention. See In re Bond, 910 F.2d 831, 832, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990); see also Atlas Powder Co. v. E.I. DuPont de Nemours & Co., 750 F.2d 1569, 1574 (Fed. Cir. 1984). Anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference or embodied in a single prior art device or practice. See In re Spada, 911 F.2d 705 (Fed Cir. 1990); see also Minnesota Min. & Mfg. Co. v. Johnson & Johnson Orthopedics, Inc., 976 F.2d 1559 (Fed Cir. 1992). Therefore, in order to avoid rejection for anticipation, it is only necessary to show that a claim contains at least one element not disclosed in a single prior art reference.

In column 7, lines 26-29, Nakoneczny discloses a wick type liquid dispensing device for dispensing and diffusing liquids and vaporizable material at a continuous slow controlled rate. The device consists of a reservoir containing the liquid and a wick to convey the liquid from the reservoir to a diffusing emanator. The wick extends from within the reservoir and transports the liquid by capillary action to the emanator at the opposite end of the wick (column 7, lines 53-60).

In comparison, the present invention with reference to claims 10-13 and 22-25 discloses an apparatus for transdermal delivery of a substance for the treatment of Parkinson's disease. The present system comprises a storage compartment and a dermal patch that is in fluid communication with the storage compartment as recited in claims 10 and 22. The dermal patch is attached to a portion of the patient's skin and the fluid flows from the storage compartment to the patient via a plurality of hollow capillaries in the dermal patch, which allows the dispensed liquid to be spread evenly as recited in claims 11 and 23. A valve regulates the flow and the flow can be transmitted from the reservoir to the patch by quantities determined by a timer as recited in claims 12 and 24. The driving force responsible for transporting the fluid in the case of Nakoneczny is the capillary action, whereas in the present invention the fluid is transported via relatively wide tubing, where the driving force can be gravitation, mechanical pressure on the reservoir made up of flexible material, or a pump. This arrangement enables the transfer of viscous liquids, whereas in the case of Nakoneczny the wick and the capillary action will not

support a viscous liquid. The hollow capillaries, as described in the present invention, serves to spread the liquid evenly in the patch and not as a driving force for the liquid. In addition, in the case of Nakoneczny, the continuous flow of fluid is a critical component of the invention and the wick is there to enable the continuous flow. In contrast, in the present invention, a continuous flow is not critical to the invention. The regulating valve determines both the quantity of the transferred liquid and the time intervals, which only in one specific case could be continuous. The uniformity obtained with the device described in the present invention is far better than that which could be obtained by a wick. Accordingly, there is no similarity between the two devices and therefore the present invention could have not been anticipated from Nakoneczny. In addition, the combination of a reservoir and a dispenser, which combines non-wick tubing and hollow capillaries that spread the liquid evenly, is novel and could not have been anticipated by Nakoneczny.

Nakoneczny clearly does not anticipate the present invention since Nakoneczny's invention is a wick type liquid dispenser, which uses a wick and not a tube to dispense the liquid from the reservoir to the emanator. Subsequently, Nakoneczny is limited to dispersing only liquid while the present invention can disperse a thick paste as well. As stated in Column 6, lines 43-46, the primary object of Nakoneczny is "the slow controlled dispensing and diffusion of liquids and vaporizable material over an extended period of time" and uses a wick to convey the liquid by capillary action, which demonstrates that it is not meant to be used with a thick paste. In the present invention, a thick paste can be dispersed from the storage compartment by applying mechanical pressure or by increasing the flow rate. Nakoneczny cannot do either nor does it disclose a way by which a thick paste can be transmitted. *not claimed*

Also, Nakoneczny's invention device comprises a reservoir and a wick. In contrast claims 10 and 22 recite an apparatus comprising a storage compartment and a dermal patch in fluid communication with said storage compartment. Claims 11 and 23 further require that the patch includes hollow capillaries to allow the liquid to be spread evenly under the patch. Nakoneczny does not have hollow capillaries and therefore does not anticipate claims 11 and 23.

Nakoneczny also fails to disclose a valve to regulate the flow of the fluid from the reservoir, and hence cannot cooperate with a timer to dispense a certain quantity at a time as

included in the present invention. In column 6, lines 56-62, Nakoneczny discloses that the method of controlling the slow uniform rate of dispensing the liquid is by selecting the length and diameter of the wick. Although varying the dimensions of the wick changes the flow rate, it cannot be done while the liquid is being dispersed, unlike the valve. The present invention is not limited to a uniform flow once transmission is commenced as Nakoneczny discloses. Rather, the flow can be regulated multiple times during the transmission. A device using a wick cannot be regulated to the extent that one with a tube can be. Accordingly, Nakoneczny does not anticipate claims 13 and 25 because Nakoneczny does not disclose a device comprising a regulating valve for controlling the flow of fluid as positively recited in claims 13 and 25.

Furthermore, Nakoneczny discloses a method for dispensing liquid in a slow, controlled uniform rate whereas the present invention simply controls the quantity of liquid that is dispersed to the patch in a controlled manner and is not limited to a particular flow rate. The present invention is not limited to a slow rate nor is the rate necessarily uniform. It simply allows the user to control the flow rate.

Applicants also maintain that the claimed invention is not obvious over Nakoneczny. The basic considerations that apply to obviousness rejections under MPEP § 2141 are as follows:

- (1) the claimed invention must be considered as a whole;
- (2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
- (4) reasonable expectation of success is the standard by which obviousness is determined.

When the prior art itself fails to meet even one of the above criteria the cited art does not satisfy 35 U.S.C. § 103(a) and prevents the establishment of the required *prima facie* case of obviousness by the Examiner. See In re Oetiker, 977 F.2d 1443, 1445 (Fed. Cir. 1992); see also In re Rijckaert, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). Moreover, to establish the required case of *prima facie* obviousness, the Examiner is required to demonstrate that the prior art discloses or suggests all the critical elements of the invention, without reference to applicants'

specification, and that the existence of these elements enables one skilled in the art to practice the invention. See In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991). It is respectfully suggested that the prior art cited by the Examiner cannot accomplish this task. Moreover, if the prior art methodology must be modified in any way to practice the instant invention the prior art citation must *also* render obvious these modifications or provide a reasonable expectation for the successful practice of the invention with the necessary modifications. See id.

In the instant case, the present invention, when considered as a whole, is not obvious over Nakoneczny. The instant invention supplies medicinal fluid to a patient via a dermal patch. The medicinal fluid is stored in a storage compartment, the storage compartment is attached by a tube to a dermal patch replete with hollow capillaries, and the medicinal fluid flows through the hollow capillaries of the dermal patch for ultimate absorption through the skin. The user can control the flow of the medicinal fluid with a valve that controls the amount of liquid that is allowed to flow from the storage compartment into the patch. The valve can be used to increase the flow rate by allowing more fluid to flow through the tube, and if necessary, a pump or mechanical pressure can also be used to increase the flow rate.

In Nakoneczny, the fluid is transferred from the reservoir to the emanator by a wick using capillary action. The only way to change the flow rate of the liquid is by altering the dimensions of the wick. Nakoneczny fails to disclose a tube to transfer the liquid, a valve to control the flow of the liquid as well as the patch that disperses the liquid evenly by hollow capillaries.

Accordingly, applicants maintain that the claimed invention is not obvious over Nakoneczny because it is not obvious to replace the wick with a tube, changing the controlling law of science from capillary action to the force of gravity or a pump. Since Nakoneczny uses capillary action to transmit the fluid, it does not make it obvious to add a valve to control the amount of fluid dispensed. It is also not obvious to add a patch for absorbing the liquid through the skin and Nakoneczny further does not render obvious a patch including hollow capillaries to evenly disperse the liquid for absorption.

For all of the foregoing reasons, the claimed invention is neither disclosed nor suggested by the cited art. Accordingly favorable reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

Applicants respectfully submit that this application is in condition for allowance. Early and favorable action is earnestly solicited. No fee, other than the fee for a one-month extension of time, is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is due, the amount of such fee may be charged to Deposit Account No. 19-4709.

Respectfully submitted,

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